



Billing Code 4210-67

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 60

[Docket No FR-5888-P-01]

Federal Policy for the Protection of Human Subjects

AGENCY: Office of the Assistant Secretary for Policy, Development and Research, HUD.

ACTION: Proposed rule.

SUMMARY: On September 8, 2015, 16 Federal departments and agencies published a proposed rule pertaining to Federal Policy for the Protection of Human Subjects. Due to certain statutory prepublication requirements applicable to HUD rules, HUD was unable to be a signatory to the September 8, 2015, proposed rule. Through this HUD proposed rule, HUD adopts the September 8, 2015, proposal and solicits public comment on the proposal.

DATES: Comment Due Date: No later than 5:00 pm on December 7, 2015.

ADDRESSES: You may submit comments, identified by docket ID number HHS-OPHS-2015-0008, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Enter the above docket ID number in the "Enter Keyword or ID" field and click on "Search." On the next Web page, click on "Submit a Comment" action and follow the instructions.
- *Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions] to:* Jerry Menikoff, M.D., J.D., OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Barry L. Steffen, Policy Development Division, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street SW, Room 8114, Washington, DC 20410–8000, telephone 202–402-5926. (This is not a toll-free number.) Persons with hearing- or speech-impairments may access this number through TTY number by calling the Federal Relay Service number at 800–877–8339 (this a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

The Federal departments and agencies that were signatories to the proposed Common Rule, published on September 6, 2015, at 80 FR 53933, and HUD (collectively the “Federal Agencies”), through this proposed rule are proposing revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was promulgated as a Common Rule in 1991. The Federal Agencies seek comment on proposals to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. The September 8, 2015, proposal is an effort to modernize, simplify, and enhance the current system of oversight. The Federal Agencies propose these revisions to the regulations governing the protection of human subjects because they believe these changes would strengthen protections for research subjects while facilitating important research.

Federal regulations governing the protection of human subjects recognize that individuals who are the subjects of research may be asked to contribute their time and assume risk to

advance the research enterprise, which benefits society at large. Federal regulations governing the protection of human subjects in research have been in existence for more than three decades. The Department of Health, Education, and Welfare (HEW) first published regulations for the protection of human subjects in 1974, and the Department of Health and Human Services (HHS) revised them in the early 1980s. During the 1980s, HHS began a process that eventually led to the adoption of a revised version of the regulations by 15 U.S. Federal departments and agencies in 1991. The purpose of this effort was to promote uniformity, understanding, and compliance with human subject protections as well as to create a uniform body of regulations across Federal departments and agencies (subpart A of 45 CFR part 46), often referred to as the “Common Rule for the Protection of Human Subjects” or more succinctly the “Common Rule.”

Since the Common Rule was promulgated, the volume and landscape of research involving human subjects has changed considerably. Research with human subjects has grown in scale and become more diverse. Examples of developments include: an expansion in the number and type of clinical trials, as well as observational studies and cohort studies; a diversification of the types of social and behavioral research being used in human subjects research; increased use of sophisticated analytic techniques for use with human biospecimens; and the growing use of electronic health data and other digital records to enable very large data sets to be analyzed and combined in novel ways. Yet these developments have not been accompanied by major change in the oversight system of research involving human subjects, which has remained largely unchanged over the last two decades.

The goals of the September 8, 2015, proposed rule are to address overdue changes to the Common Rule; specifically to increase human subjects’ ability and opportunity to make informed decisions; reduce potential for harm and increase justice by increasing the uniformity

of human subject protections in areas such as information disclosure risk, coverage of clinical trials; and facilitate current and evolving types of research that offer promising approaches to treating and preventing medical and societal problems through reduced ambiguity in interpretation of the regulations, increased efficiencies in the performance of the review system, and reduced burdens on researchers that do not appear to provide commensurate protections to human subjects. It is hoped that these changes will also build public trust in the research system.

The full description of the Federal Agencies' proposal is set out in the September 8, 2015 rule. By cross-reference to the September 8, 2015, proposed rule, HUD advises of its adoption of this proposal and solicits comment from HUD program participants and the general public on the September 8, 2015, proposed Common Rule. HUD's regulation on the Protection of Human Subjects is found in 24 CFR part 60. HUD's regulation on this subject cross-references to the HHS regulations in 45 CFR part 46. HUD's regulation at § 60.101, entitled "Cross-reference," reads as follows: "The provisions set forth at 45 CFR part 46, subpart A, concerning the protection of human research subjects, apply to all research conducted, supported, or otherwise subject to regulation by HUD."

II. HUD's Proposed Regulatory Text – No Change Proposed

HUD's current regulations on the protection of human subjects are, by cross-reference, the regulations on the protection of human subjects promulgated by HHS, and this proposed rule would apply that approach to the September 8, 2015, proposed Common Rule published by 16 U.S. Federal departments and agencies.

III. Findings and Certifications

Environmental Impact

This rule does not direct, provide for assistance or loan and mortgage insurance for, or

otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this rule is categorically excluded from environmental review under the National Environmental Policy Act (42 U.S.C. § 4321).

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. This proposed rule does not impose any federal mandates on any state, local, or tribal governments or the private sector within the meaning of UMRA.

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either (1) imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or (2) preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This rule would not have federalism implications and would not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

List of Subjects for 24 CFR Part 60

Human research subjects, Reporting and recordkeeping requirements.

Dated: September 9, 2015

Katherine M. O'Regan, Assistant Secretary for
Policy Development and Research

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